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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,483	03/19/2001	Yoshinobu Hanyu	P20757	8955

7055 7590 01/15/2002

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1655	9

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/810,483	Hanyu et al.
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- *If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.*
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1) ☒ *Responsive to communication(s) filed on Nov 21, 2001 .*

2a) ☒ *This action is* **FINAL.** 2b) ☐ *This action is non-final.*

3) ☐ *Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

Disposition of Claims

4) ☒ *Claim(s) 33-54 is/are pending in the application.*

4a) *Of the above, claim(s) _____ is/are withdrawn from consideration.*

5) ☐ *Claim(s) _____ is/are allowed.*

6) ☒ *Claim(s) 33-54 is/are rejected.*

7) ☐ *Claim(s) _____ is/are objected to.*

8) ☐ *Claims _____ are subject to restriction and/or election requirement.*

Application Papers

9) ☐ *The specification is objected to by the Examiner.*

10) ☐ *The drawing(s) filed on _____ is/are objected to by the Examiner.*

11) ☐ *The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.*

12) ☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

13) ☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

a) ☐ *All* b) ☐ *Some** c) ☐ *None of:*

1. ☐ *Certified copies of the priority documents have been received.*
2. ☐ *Certified copies of the priority documents have been received in Application No. _____ .*
3. ☐ *Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).*

**See the attached detailed Office action for a list of the certified copies not received.*

14) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

15) ☒ *Notice of References Cited (PTO-892)*

16) ☐ *Notice of Draftsperson's Patent Drawing Review (PTO-948)*

17) ☐ *Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____*

18) ☐ *Interview Summary (PTO-413) Paper No(s). _____*

19) ☐ *Notice of Informal Patent Application (PTO-152)*

20) ☐ *Other:*

DETAILED ACTION

Specification

1. Rejected claims 25-32 have been canceled and new claims 33-54 have been added.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 33-54 are rejected under 35 U.S.C. 103 (a) over Maa et al. (U.S. Patent 6,284,282 B1) (September 4, 2001) in view of Knight et al. (U.S. Patent 6,017,549) (January 25, 2000).

Maa et al. teach a powder containing a physiologically active peptide, wherein the powder is made up of particles comprising a physiologically active peptide and mannitol at a weight proportion of 1:1 to 1:50 (Table 3), the particles further comprising nonionic surfactant (Column 1, lines 54-60) and a nonionic, organic, water soluble binder (trehalose in this case, Table 3). Maa et al. teach that the ratio of physiologically active peptide and mannitol is precisely 1:1 (Column 21, lines 22-23).

Maa et al. teach a powder containing a physiologically active peptide, for which drying of the aqueous liquid was performed by spray-freeze drying. (Figure 8, Example 1 and Tables 1 and 2).

Maa et al. teach a powder containing a physiologically active peptide, wherein the physiologically active peptide is human growth hormone (Column 1, lines 54-60 and Column 3, lines 53-67).

Maa et al. teach the composition, wherein the average size of the particles is 1-10 micrometer (Column 4, lines 1-22).

Maa et al. teach an inhalant composition containing a physiologically active peptide (Column 4, lines 1-22).

Maa et al. teach the powder, wherein the physiologically active peptide comprises human insulin (Column 10, line 56 to Column 11, line 14).

Maa et al do not teach the nonionic surfactant in an amount of 0.05-3 parts by weight and a nonionic, organic, water soluble binder in an amount of 0.05-6 parts by weight.

However, it is *prima facie* obvious that selection of the specific ratio of weights of surfactant and binder represents routine optimization with regard to sequence, length and compositions of physiologically active peptide, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the weight ratio selection of ingredients of the powder was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Maa et al do not teach the hydrogenated lecithin as one of the ingredients of the composition.

Knight et al teach the hydrogenated lecithin as one of the ingredients of the composition (Column 2, lines 52-58, and Claim 13).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the hydrogenated lecithin as one of the ingredients of the composition of Knight et al into the powder composition of Maa et al, since Maa et al. state, "The present invention is directed to methods and compositions comprising

spray freeze-dried formulations of therapeutic proteins, that show good dispersibility and respirable properties, as well as good stability (Column 3, line 53-56)." Knight et al further provides motivation as Knight et al state, "In particular the invention relates to cosmetic and pharmaceutical emulsions which are non-irritating when applied to the skin (Column 1, lines 7-9). By employing scientific reasoning, an ordinary artisan would have combined and substituted the hydrogenated lecithin composition of Knight et al. into the inhalant powder composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Maa et al in order to improve the inhalant growth factor drug formulation. An ordinary practitioner would have been motivated to combine and substitute the hydrogenated lecithin composition of Knight et al. into the inhalant powder composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Maa et al in order to achieve the express advantages, as noted by Maa et al., of an inhalant drug comprising spray freeze-dried formulations of therapeutic proteins, that show good dispersibility and respirable properties, as well as good stability and also to achieve the express advantages, as noted by Knight et al., of an invention that relates to cosmetic and pharmaceutical emulsions which are non-irritating when applied to the skin.

Response to Amendment

4. In response to amendments, all 112 (second paragraph) rejections and 102(b) as well as related 103 (a) rejections are hereby withdrawn. However, a new 103 (a) rejection has been included.

Response to Arguments

5. Applicant's arguments with respect to new claims 33-54 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to

Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

January 8, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600